



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,249	06/25/2003	Leonardus H.T. Van der Ploeg	20561YDA	3677

210 7590 07/05/2006

MERCK AND CO., INC
P O BOX 2000
RAHWAY, NJ 07065-0907

EXAMINER

FALK, ANNE MARIE

ART UNIT PAPER NUMBER

1632

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/603,249

Applicant(s)

VAN DER PLOEG ET AL.

Examiner

Anne-Marie Falk, Ph.D.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-32 and 36-57 is/are pending in the application.
- 4a) Of the above claim(s) 30-32, 36-46, 49 and 54-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47, 48 and 50-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/30/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed April 3, 2006 has been entered.

Applicants' election, with traverse, of Group IV, Claims 47, 48, and 50-53 in the response filed April 3, 2006 is acknowledged. The elected invention is drawn to a method for determining whether a substance is capable of binding to the melanocortin-3 receptor (MC-3R), a method for determining whether a substance is capable of activating MC-3R and regulating body weight, a method for determining whether a substance is a potential agonist or antagonist of MC-3R and regulates body weight, and a method for determining whether a substance is capable of binding to MC-3R and regulating body weight. The traversal is on the grounds that Groups IV and V should be examined together. Applicants state that there is no undue burden to search for a method of identifying a substance which modulates the human MC-3R (SEQ ID NO: 4, as recited in Claim 49, when a method of identifying a substance which modulates MC-3R (not specific to a particular species) must be searched and considered at the same time. The issue is not that Claim 49 recites a particular species and that the claims of Group IV are broadly drawn to any MC-3R of the genus, but rather relates to the type of assay being performed, which are distinct. The methods of the the invention of Group IV are patentably distinct from the method of the invention of Group V because the inventions are drawn to distinct methods that require different starting materials, different modes of operation, and produce different effects. The method of the invention of Group V requires the use of purified protein, whereas the method of the invention of Group IV requires the use of test cells. Thus, the starting materials differ substantially. Furthermore, such assays differ substantially in their mode of operation and effect produced. A purified protein cannot be assayed in the same manner as test cells. The searches required for the inventions are not coextensive. A search for an assay method that uses test cells to look at receptor activity would not likely identify art relating to binding assays that use purified protein. Thus, additional searching would be required to cover the invention of Group V. Likewise, a search for binding assays that use purified protein would not likely

Art Unit: 1632

identify art relating to assay methods that use test cells to look at receptor activity. Therefore, a search and examination of both inventions in a single patent application does impose a serious burden on the Office.

The requirement is still deemed proper and is therefore made FINAL.

Claims 30-32 and 36-57 remain pending in the instant application.

Claims 30-32, 36-46, 49, and 54-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction requirement in the reply filed on April 3, 2006.

Accordingly, Claims 47, 48, and 50-53 are examined herein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 47, 48, and 50-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Fong et al. (1997, Biochemical and Biophysical Research Communications 237: 629-631; cited on the IDS filed 1/30/06, citation no. U).

Fong et al. (1997) disclose that agouti related protein (ART) is an antagonist of the human MC-3 and MC-4 receptors. ART was expressed as a secreted protein in COS-7 cells and was shown to be functionally active in inhibiting the binding of a radiolabeled α -melanocyte stimulating hormone (α -MSH) analog to the human melanocortin-3 (MC-3) and melanocortin-4 receptors. Binding assays were carried out using membranes prepared from L cells stably expressing human MC-3R (page 630, column 1, paragraph 1). Since L cells are a mouse cell line, it is clear that the cells were transfected to express the

Art Unit: 1632

human MC-3R, and therefore this teaching is inherent in the reference. Intracellular cAMP levels were measured by radioimmunoassay (page 630, column 1, paragraph 2). The α -MSH analog acts as a ligand for the MC-3 and MC-4 receptors. Thus, ART corresponds to the test substance as recited in the instant claims. The reference further discloses that the data suggest that ART may be a physiological regulator of feeding behavior. Thus, Fong et al. carried out the assays as instantly claimed.

Thus, the claimed invention is disclosed in the prior art.

Conclusion

No claims are allowed.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 10:30 AM to 7:00 PM.

Art Unit: 1632

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER